

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-143

FINAL PRINTED LABELING

Trivagizole 3TM

Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

3 Day Treatment

Vaginal Cream

1 Reusable Applicator

Trivagizole 3TM

Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

Vaginal Cream

Cures Most Vaginal Yeast Infections

Trivagizole 3TM

Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

Vaginal Cream

One 25 g (0.88 oz) Tube Of Clotrimazole Vaginal Cream (2%)
and 1 Reusable Applicator

Cures Most
Vaginal Yeast
Infections

3 Day Treatment



Educational Brochure Enclosed



Questions or comments? Call toll-free, 1-888-827-6222, for our 24 hour automated response system.

Inactive ingredients benzyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate-60, purified water, sorbitan monostearate

Other information
■ The tube opening should be sealed. If seal has been broken, do not use product.
■ See and date of carton and tube for lot number and expiration date.
■ Store at 20-25°C (68-77°F)

Drug Facts (continued)

Time for
continued panel
8 pt Helvetica Bold Italic

Distributed by:
Taro Pharmaceuticals
U.S.A., Inc.
Hawthorne, NY 10532
Made in Canada
Taro is a registered trademark of
Taro Pharmaceuticals U.S.A. Inc.
www.taropharma.com

Drug Facts

Active ingredient (in each applicator)
Clotrimazole 100 mg (2%)
Vaginal antifungal

Use
Treats vaginal yeast infections

Warnings
For vaginal use only

Do not use
■ If you have never had a vaginal yeast infection diagnosed by a doctor
■ If you have a fever (higher than 100°F), pain in the lower abdomen, back, or a foul-smelling vaginal discharge. You should see a doctor for treatment of these symptoms.
■ Ask a doctor before use if you have
■ vaginal itching and discomfort for the first time
■ symptoms that return within 2 months. You could be pregnant, or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system (which may be due to HIV - the virus that causes AIDS).

When using this product
■ do not use tampons, douches, or spermicides
■ do not use condoms or diaphragms, as this product may damage them and they may not prevent sexually transmitted disease or pregnancy

Stop use and ask a doctor if
■ symptoms do not get better in 3 days
■ symptoms last more than 7 days
■ you get a rash, fever, abdominal pain, or a foul-smelling vaginal discharge

Directions
■ Before using, read and keep the enclosed educational brochure for complete instructions and information
■ adults and children 12 years and over:
■ insert one applicatorful of cream into the vagina at bedtime for 3 days in a row
■ children under 12 years: ask a doctor

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Time for
continued panel
8 pt Helvetica Bold Italic
8 pt Helvetica Bold
6 pt Helvetica Bold
left justified
6 pt Helvetica Bold
left justified
8 pt Helvetica Bold
left justified
Headings:
with 6.5 pts. leading, left justified
Body text:
6 pt Helvetica Regular
10 pt Helvetica Bold
italic, left justified

3 Day Treatment
1 Reusable Applicator
Cures Most Vaginal Yeast Infections

3/22/2000

MAR 22 2000

CAP END

127 mm
TUBE
LENGTH

OPEN END

TARO

TARO

Trivagizole³™

Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

3 Day Treatment

Net Weight 25g (0.88oz)

For vaginal use only. Do not use in eyes or take by mouth.

If this is the first time you have had vaginal itching and discomfort, consult your doctor. If you have had a doctor diagnose a vaginal yeast infection before and have the same symptoms now, use this cream as directed for 3 days in a row.

Warnings: Read the Warnings and Directions on the carton and in the educational brochure before using this product.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: To Open: Unscrew the cap, use pointed end on cap to break seal.

Fill the applicator and insert one applicatorful of cream into vagina at bedtime for 3 days in a row.

Active Ingredient: Clotrimazole 2% (100 mg per applicator)

Store at 20-25°C (68-77°F).

See end of tube for lot number and expiration date.

Safety Sealed: The tube opening should be sealed. If seal has been broken, do not use product.

Mfd. by: Taro Pharmaceuticals Inc.

Bramalea, Ontario, Canada L6T 1C3

Made in Canada PK-0000-0

MAR 22 2000

ID BAR CODE

EDUCATIONAL BROCHURE

**Read This
Before Using**

**Trivagizole 3™
Clotrimazole
Vaginal
Cream (2%)
Vaginal Antifungal**

Clotrimazole 2% (100 mg per applicator)

**3-day treatment of
vaginal yeast
infections.**

Use:

- For the treatment of vaginal yeast infections.

If you have symptoms such as vaginal itching, burning, or discharge, and if at some time in the past your doctor has told you that these symptoms were due to a vaginal yeast infection, then Trivagizole 3 Vaginal Cream should work for you. If, however, you have never had these symptoms or a vaginal yeast infection before, you should see your doctor before using this product.

**What is a
Vaginal Yeast Infection?**

A yeast infection is a common type of vaginal infection. Your doctor may call it candidiasis. This condition is caused by an

organism called Candida, which is a type of yeast. Healthy women usually have this yeast on the skin, in the mouth, in the digestive tract, and in the vagina. At times, the yeast can grow very quickly. In fact, the infection is sometimes called yeast (*Candida*) "overgrowth." Some women may have a yeast infection on the skin outside the vagina (vulva) associated with the vaginal infection.

A yeast infection can occur at any age. It is most common during the childbearing years. Women who are pregnant or diabetic, taking antibiotics, birth control pills or steroids, or who have a weakened immune system are more likely to get repeated yeast infections.

Various medical conditions can damage the body's normal defenses against

infection. One of the most serious of these conditions is infection with the human immuno-deficiency virus (HIV-the virus that causes AIDS). The HIV virus causes the body to be more likely to get infections, including vaginal yeast infections. Therefore, women with HIV infection may have frequent vaginal yeast infections that do not clear up easily with proper treatment. If you may have been exposed to HIV and are experiencing repeated vaginal yeast infections, you should see your doctor right away. For additional information on HIV infection, please contact your doctor or the CDC National AIDS HOT-LINE. The CDC phone numbers are: 1-800-342-AIDS (English), 1-800-344-7432 (Spanish), or 1-800-243-7889 (hearing impaired, TDD)

**Symptoms of a Vaginal
Yeast Infection**

There are many symptoms of a vaginal yeast infection. They can include:

- Vaginal itching (ranging from mild to severe).
- A clumpy, vaginal discharge that may look like cottage cheese.
- Vaginal soreness, irritation, or burning.
- Rash or redness on the skin outside the vagina (vulvar irritation).

Note: Vaginal discharge that is different from above, for example, a yellow/green discharge or a foul-smelling discharge may mean that you have a different infection. If this is the case, you should talk to your doctor before using Trivagizole 3 Vaginal Cream.

Warnings

- For vaginal use only. Do not use in eyes or take by mouth.
- This product is effective only in treating vaginal yeast infections.
- Do not use Trivagizole 3 Vaginal Cream if you have any of the following symptoms:
 - fever (higher than 100°F).
 - pain in the lower abdomen, back, or either shoulder.
 - a foul-smelling vaginal discharge.
- While using Trivagizole 3 Vaginal Cream, if you get a fever, abdominal pain, or a foul-smelling vaginal discharge, stop

using the product and contact your doctor right away. You may have a more serious disease.

- If your symptoms do not improve in 3 days, or you still have symptoms after 7 days, you should call your doctor.
- If your symptoms return within 2 months, you should talk to your doctor. You could be pregnant or there could be a serious underlying medical cause for your infections, including diabetes or a weakened immune system (which may be due to HIV - the virus that causes AIDS).
- Contact your doctor if you get hives or a skin rash while using this product.

MAR 22 2000

Side Effects

A mild increase in vaginal burning, itching, or irritation may occur when Trivagizole 3 Vaginal Cream is inserted. Stop using Trivagizole 3 Vaginal Cream and talk to your doctor if you have abdominal pain, hives, or skin rash, or if you have severe vaginal burning, itching, or irritation.

For Best Results

1. Be sure to use this product for the full 3 days, even if your symptoms go away sooner.
2. Use one applicatorful of Trivagizole 3 Vaginal Cream at bedtime for three days in a row, even during your menstrual period.
3. Wear cotton underwear.
4. If your partner has itching, redness or discomfort of his penis, he should consult his doctor. He should tell the doctor that you are treating

yourself for a vaginal yeast infection.

5. Dry the outside vaginal area thoroughly after a shower, bath or swim. Change out of a wet bathing suit or damp clothes as soon as possible. A dry area is less likely to lead to the growth of yeast.

6. Wipe from front to rear after a bowel movement or urination.

7. Do not douche unless your doctor tells you to do so. Douching may wash the product out of the vagina.

8. Try not to scratch the skin outside the vagina. Scratching can cause more irritation and can spread the infection.

9. Discuss with your doctor any drugs you are now taking. You are more likely to get a vaginal yeast infection with certain drugs.

10. Do not have vaginal intercourse while using this product.

If you have a Question

Questions of a medical nature should be taken up with your doctor. If you have any other questions, or need more information on this product, call our 24 hour automated response system, TOLL-FREE, at 1-888-827-6222, Monday through Friday.

Active Ingredient:

Clotrimazole 2% (100 mg per applicator)

Inactive Ingredients:

Benzyl alcohol, cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 60, purified water, sorbitan monostearate.

Storage

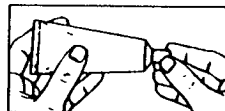
Store at 20-25 C (68- 77 F). See end flap of carton and end of tube for lot number and expiration date.

How to use Trivagizole 3 Vaginal Cream with 1 Reusable Applicator

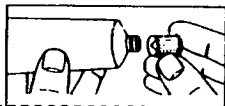
Directions for Use

Use the cream at bedtime for 3 days in a row. Read the full directions below before using.

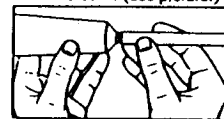
1. To open the tube, unscrew the cap.



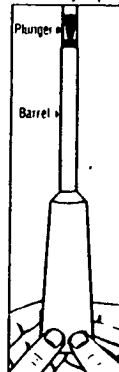
Press the sharp point of the cap into the sealed end of the tube. Push down firmly until the seal is broken (see picture).



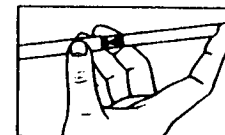
2. Attach the applicator to the tube of cream by placing end of the applicator firmly onto tube of cream. (see picture.)



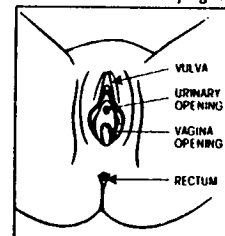
3. Gently squeeze the cream into the applicator. Continue squeezing until line on plunger marked "FULL" reaches end of barrel. Separate the applicator from the tube. After each use, replace cap and roll up the tube from the bottom.



4. Hold the barrel as shown in the picture.

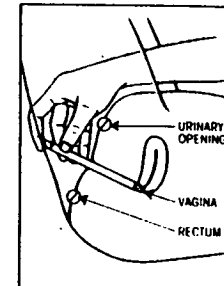


5. The Trivagizole 3 Vaginal Cream applicator is inserted into the vagina in much the same way as a tampon. Gently insert the applicator into the vagina as far back as it will go comfortably. This can be done while lying on



your back with your knees bent (as shown in the picture), or while standing with your feet apart and your knees bent.

6. With one hand holding the



barrel, use the other hand to push the plunger into the barrel as far as it will go. Remove the applicator from the vagina.

7. Clean the applicator after each use. Pull the two pieces apart. Wash them with soap

FPO